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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,765	02/04/2004	Thomas Ryan	GYN-5011	3673

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EXAMINER

TOY, ALEX B

ART UNIT PAPER NUMBER

3739

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/771,765	<b>Applicant(s)</b> RYAN, THOMAS	
	<b>Examiner</b> Alex B. Toy	<b>Art Unit</b> 3739	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 4, 8, 11, 16 and 20-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 9, 10, 12-15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/25/04; 5/31/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Invention I (claims 1-19 and 24-25) in the reply filed on June 5, 2006 is acknowledged. Claims 20-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

New claim 26 is also withdrawn on the same grounds as stated in the original Election/Restriction requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19 and 24-25, drawn to a device for ablating a body cavity, classified in class 606, subclass 27.
- II. Claims 20-23 and 26, drawn to a method for ablating a uterus, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as ablating a body cavity other than the uterus.

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Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

It is noted that new claim 26 is not substantially the same as claim 1, since claim 26 is a method for treating specifically the uterus, while claim 1 is an apparatus for treating any body cavity. Therefore, claim 1 does not require the specifics of claim 26 and is patentably distinct under the criteria stated above.

Applicant's election with traverse of claims 1-3, 5-7, 9-10, 12-15, 17-19, and 26 in the reply filed on June 5, 2006 is acknowledged. The examiner agrees to applicant's request that the species be delineated as follows: Species I (Figs. 1, 2, 4, and 6a-d) and Species II (Figs. 5 and 5a).

In summary, claims 4, 8, 11, 16, and 20-26 are withdrawn from further consideration. Claims 1-3, 5-7, 9-10, 12-15, and 17-19 are examined.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, 9-10, 12-15, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Stern (U.S. Pat. No. 6,041,260).

Regarding claim 1, Stern discloses a device for ablating a body cavity comprising:

an introducer 16 having a distal end and a proximal end and at least one channel 18 therethrough (Figs. 1-2);

a distendable bladder 14 coupled to the distal end and being distendable within the body cavity from a substantially deflated state to an inflated state wherein it approximates an interior of at least a portion of said body cavity that is to be ablated (col. 4, ln. 34-38 and Figs. 1-2);

an inflation device coupled to the proximal end and in fluid communication with the at least one channel and with an interior of the distendable bladder, wherein activation of the inflation device causes an inflation medium to flow through the at least one channel and into the distendable bladder to thereby inflate the distendable bladder (col. 4, ln. 34-38, col. 7, ln. 7-9, and Figs. 1 and 10a); and

at least one flexible resistive element 40 coupled to the distendable bladder (col. 5, ln. 38-44 and Fig. 4a), the resistive element being electrically coupleable to a voltage source and emitting resistive heat when so coupled (col. 5, ln. 44-48 and Abstract), the resistive element being coupled to the distendable bladder in a manner so as not to impair movement of the bladder from the deflated to the inflated states (col. 5, ln. 41-44 and Fig. 4a).

Since the resistive elements 40 on the balloon are segmented and Stern clearly discloses that the balloon is designed to inflate and deflate, the resistive elements are inherently coupled to the distendable bladder in a manner so as not to impair movement

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of the bladder from the deflated to the inflated states. In addition, resistive elements must be inherently flexible since they allow the balloon to expand and conform to the expanded balloon surface.

Regarding claims 2 and 3, Stern discloses the device of claim 1, wherein the at least one resistive element is coupled to an inner or outer surface of the distendable bladder (col. 5, ln. 38-44).

Regarding claims 5-7 and 10, Stern discloses the device of claims 1 and 9, wherein one or a plurality of flexible resistive elements 170, 172 is coupled to the distendable bladder along a serpentine path so as to cover a predetermined portion(s) of a surface area of the bladder (col. 6, ln. 59-65 and Fig. 9), and wherein when the distendable bladder is in the inflated state, the first and second resistive elements are in thermal contact with first and second portions of the endometrial lining of the uterus (Fig. 1).

Regarding claim 9, Stern discloses the device of claim 1, wherein the body cavity is the uterus, and wherein, when in the inflated state, the distendable bladder approximates an interior of the uterus (col. 4, ln. 34-38 and Fig. 1).

Regarding claims 12-14, Stern discloses the device of claim 1, wherein the inflation medium is a fluid, gas, or air (col. 4, ln. 34-38).

Regarding claim 15, see the preceding rejection of claim 1.

Regarding claim 17, see the preceding rejection of claims 9 and 15.

Regarding claims 18 and 19, see the preceding rejection of claim 15 and Fig. 1.

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**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 4949718 A	USPAT	Neuwirth; Robert S. et al.
US 5443470 A	USPAT	Stern; Roger A. et al.
US 5769880 A	USPAT	Truckai; Csaba et al.
US 6041260 A	USPAT	Stern; Roger A. et al.
US 6425877 B1	USPAT	Edwards; Stuart D.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953.

The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*  
8/16/06

*Roy D. Gibson*  
ROY D. GIBSON  
PRIMARY EXAMINER